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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,827	09/12/2003	Andreas Hartlep	SCHWP0177USA	7728

7590 12/31/2007
RENNER, OTTO, BOISSELLE & SKLAR, LLP
Nineteenth Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

EXAMINER

CHAO, ELMER M

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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12/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/661,827

Applicant(s)

HARTLEP ET AL.

Examiner

Elmer Chao

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/5/2007 has been entered.

Drawings

2. The drawings were received on 12/5/2007. These drawings are accepted.

Response to Arguments

3. Applicant's arguments with respect to **claim 1-16 and 18-22** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-12, 16, 21, and 22** are rejected under 35 U.S.C. 102(e) as being anticipated by Raghaven et al. (U.S. 6,549,803 B1).

Regarding **claims 1-4, 6, 7, 16, 21, and 22**, Raghaven et al. teach a method for identifying advantageous and non-advantageous infusion regions in a tissue, the method comprising: capturing via an imaging system functional anatomical data and/or structural anatomical data before infusion of a fluid into the tissue; evaluating the captured functional and/or structural anatomical data with computer assistance and without the use of an infusion fluid (col. 14, lines 63-66); based on the evaluating step, identifying directional channels within the tissue and determining infusion distribution information related to the identified directional channels, the identified directional channels and/or infusion distribution information being indicative of advantageous and/or non-advantageous infusion regions (col. 4, lines 1-19); and presenting identified advantageous and/or non-advantageous infusion regions for viewing by a user (col. 4, lines 20-40).

Regarding **claims 5, and 10-12**, the anatomical data is evaluated three-dimensionally and/or two-dimensionally (col. 2, lines 29-67).

Regarding **claim 8**, Raghaven et al. teach ways of identifying isotropy and anisotropy of flow directions in the regions in the tissue (col. 12, line 60 - col. 13, line 8).

Regarding **claim 9**, Raghaven et al. teach calculating a distribution volume (col. 10, lines 19-49).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 13-15, 18, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Raghaven et al., in view of Gillies et al. (U.S. 6,272,370).

Regarding **claims 13-15, 18, and 19**, Raghaven et al. teach all of the above limitations. Raghaven et al. does not explicitly teach the infusion at the selected point being planned using stereotactic planning and navigation. However, Gillies '370 teaches the use of stereotactics in combination with magnetic resonance imaging in the planning and navigation for drug delivery (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Raghaven et al. to use Gillies' '317 method to perform the infusion after the infusion site has been selected. Such a modification would produce a method of drug delivery that is more accurate and less damaging to other areas around the target area (C10, L1-9).

8. **Claims 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Raghaven et al., in view of Gillies '370, and further in view of Strommer et al. (U.S. 6,233,476 B1). Raghaven et al. and Gillies '370 teach all of the above limitations. Raghaven et al. and Gillies '370 do not explicitly teach the imaging device, processor, and the medical planning and navigation system being connected together. However,

Strommer '476 teaches a medical positioning system in which the processor, imager, and navigation system are all connected together (C4, L46-55). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Raghaven et al. and Gillies '317 such that the imaging device, the processor, and the medical planning and navigation system are connected to each other. Such a modification would allow for the location of the catheter or infusion device to be located and superimposed on the image obtained from the imager (C4, L46-55).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

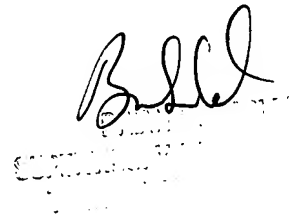
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
12/22/2007

A handwritten signature in black ink, appearing to read "B. S. C.", is written over a faint, rectangular official stamp. The stamp contains some illegible text, possibly a date or a reference number.